MEDWAVES INCORPORATED
16760 West Bernardo Drive
San Diego, CA 92127

510k: K070356
Request for Revision of 510(k) Summary
December 15, 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA1990 and 21 CFR 807.92(c).

1. Submitter Information

MedWaves Incorporated
16760 West Bernardo Drive
San Diego, California
Phone: (858) 946-0015
Fax: (858) 946-0016

Contact: Ted Ormsby

Date of preparation: December 15, 2007

2. Device Name

Trade name: MedWaves Microwave Coagulation/Ablation System

Common name: Microwave Tissue Coagulation/Ablation System

Classification name and reference: Class II, 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories, Panel 79, General and Plastic Surgery

Product Code: NEY

3. Predicate Devices

The MedWaves Microwave Coagulation/Ablation System is substantially equivalent to the following devices previously cleared via 510k by FDA:

- Microsulis Tissue Ablation (MTA) System K052919
- Tyco/Radionics Cool-Tip™ RF System K984552
- VivaWave™ Microwave Ablation System K011676
- VivaWave™ Microwave Ablation System K053535

4. Device Description

The MedWaves Microwave Coagulation/Ablation System consists of a microwave generator and accessories used for the surgical ablation of soft tissue. The accessories include two types of sterile, handheld, single use surgical coagulation/ablation probes and required connector cables. The two versions of coagulation/ablation probes include short and longer length devices.

The MedWaves microwave generator operates at a frequency of 902 to 928 MHz. For general surgery applications the generator is set by the manufacturer to deliver a maximum of 32 W and is user selectable up to 28 W. The system is capable of being run in two primary modes: power control mode and temperature control mode. A dynamic monitoring system within the generator maintains the set point selected by the user (either a power or temperature control point) in order to provide consistent and expected coagulation/ablation performance.

The system incorporates several monitored parameters that alert the user to potentially unsafe conditions during operation. These parameters and condition alerts include: high temperature, high-power, inefficient microwave delivery, catheter/probe disconnect and system errors. MedWaves microwave generator utilizes firmware to monitor these processes and post the ablation parameters and progress for the user on an LCD screen.

MedWaves uses proprietary antenna technology coupled with a delivery system that efficiently transmits the microwave energy to the tip of the probe. The microwave antenna is 20 mm long mounted at the distal end. Efficiency of the system relieves the requirement of having high powered generator in order to create the desired coagulation/ablation results. The efficiency of the system allows the incorporation of monitoring and controls on the microwave energy delivery in order to deliver the most optimal performance available.

5. Indications for Use

The MedWaves Microwave Coagulation/Ablation System is intended for general surgery use in open procedures for the coagulation and ablation of soft tissues. The system is not intended for use in cardiac procedures.

6. Performance Data in Support of Substantial Equivalence

Performance testing was carried out to ensure that the MedWaves Microwave Coagulation/Ablation System functions as intended and meets design specifications. The MedWaves Microwave Coagulation/Ablation System was subjected to a battery of electrical, mechanical, functional and biocompatibility tests. In addition, the testing demonstrates that the MedWaves Microwave Coagulation/Ablation System complies with the following standards:

Electrical Safety/EMC:	IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility IEC 60601-2-2 2007 Standard Requirement Tests
Biocompatibility:	ISO 10993, Biological Evaluation of Medical Devices
Sterility:	ANSI/AAMI/ISO 11135:1994 Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization
Packaging, Shelf Life:	AAMI ANSI ISO 11607-1:2006 Packaging for Terminally Sterilized Medical Devices

MedWaves Catheter/Probes underwent mechanical and in vitro testing in accordance with the intended use. The device performed as expected and comparable to the published performance of currently marketed products.

The MedWaves microwave generator underwent firmware testing in accordance with:

- AAMI ANSI IEC 62304 Medical Device Software – Software Lifecycle Processes
- AAMI ANSI ISO 14971 & 14971 A1 Medical Devices - Application of Risk Management to Medical Devices

Sufficient data were obtained to show the device is substantially equivalent to the predicate devices and meets safety and effectiveness criteria.

7. Substantial Equivalence Conclusion

Substantial equivalence is based on the MedWaves Microwave Coagulation/Ablation System having the same intended use and general technological characteristics as the predicate devices. There are no new fundamental technological differences between the MedWaves Microwave Coagulation/Ablation System and legally marketed devices.

There are no new questions of safety or efficacy raised by the MedWaves Microwave Coagulation/Ablation System or any of its coagulation/ablation probes. Test data supplied and published literature showed that the MedWaves Microwave Coagulation/Ablation System performed comparably to a predicate device with respect to lesion size and tissue temperatures generated. Therefore, it can be concluded that the MedWaves Microwave Coagulation/Ablation System and accessories are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2007

MedWaves Incorporated
% Mr. Ted Ormsby
President and CTO
16760 W. Bernardo Drive
San Diego, California 92127

Re: K070356
Trade/Device Name: MedWaves Microwave Coagulation/Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NEY
Dated: December 2, 2007
Received: December 4, 2007

Dear Mr. Ormsby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K070356**

Device Name: MedWaves Microwave Coagulation/Ablation System

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K070356